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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,425	02/19/2002	Harold G. Brown	2059-0103P	1812

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EXAMINER	
PRATS, FRANCISCO CHANDLER	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,425	BROWN ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *1-18,20-25,39-41,43-46,48,50-59,61-65,67 and 69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,22,23,36-38,42,47,49,60,66,68 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed December 15, 2003, has been received and entered.

Claims 1-70 are pending.

Election/Restrictions

Applicant's election with traverse, in the paper filed December 15, 2003, of the group II invention, directed to glycosaminoglycan-containing compositions which do not contain essential oils, recited in amended claims 19, 36-38, 42, 47, 49, 60, 66, 68 and 70, is acknowledged. Applicant's election of hyaluronic acid as the therapeutic compound is also acknowledged.

The traversal is on the ground(s) that the groupings in the restriction mischaracterized the invention in view of the statement "essential oil hyaluronic acid", and the groupings directed to the various disease states all "relate to inflammation" and therefore should be examined together. This is not found persuasive because, as pointed out by applicant, hyaluronic acid is clearly not an essential oil. In view of applicant's election and amendment, only those claims directed to compositions containing hyaluronic acid, but not containing an essential oil, will be examined.

As to the examination of all claims directed to disease treatments, it is respectfully pointed out that the objective of restriction practice between inventions under 35 U.S.C. § 121 is to separate the examination of inventions which are patentably distinct. That is, inventions which can properly support separate patents should be examined separately, unless the presence of more than one invention does not burden the examination process. See MPEP § 803. On the current record it appears that each of the various disease states presented in the various disease treatment claims contains different symptoms and has a different set of patients. While applicant asserts that the various disease states all "relate to inflammation", applicant has not provided or pointed to any prior art demonstrating an underlying causative mechanism tying together all of the claimed disease states such that a reference anticipating or obviating the treatment of one disease would necessarily anticipate or render obvious any and/or all of the other disease states. Moreover, applicant presumably would not concede that a reference which anticipates or renders obvious one of the claimed disease treatments would necessarily anticipate or render obvious the other claimed disease treatment, merely because all of the claimed disease conditions "relate to inflammation."

On the current record each of the inventions directed to disease treatments presents claims encompassing different patients, different symptoms, and different underlying causes, thereby requiring different searches and consideration of different issues. Thus, in addition to presenting a serious burden on the examination process because of the differing issues involved therein, the various claim groupings directed to disease treatments present patentably distinct subject matter, and are therefore properly restricted under 35 USC § 121.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-18, 20-25, 39-41, 43-46, 48, 50-59, 61-65, 67 and 69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. As noted above, applicant timely traversed the restriction (election) requirement in the paper filed December 15, 2003.

Claims 19, 22, 23, 36-38, 42, 47, 49, 60, 66, 68 and 70, are directed to compositions comprising a glycosaminoglycan in the absence of an essential oil, the invention elected by

applicant, and encompass hyaluronic acid, the species of glycosaminoglycan elected by applicant.

Claims 19, 22, 23, 36-38, 42, 47, 49, 60, 66, 68 and 70 are therefore examined on the merits.

Claim Objections

Claim 68 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Specifically, claim 68 recites that the composition does not contain an essential oil. However, claim 68 depends from claim 19, which already states that the composition cannot contain an essential oil. Therefore claim 68 cannot properly depend from claim 19.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 22, 23, 36-38, 42, 47, 49, 60, 66 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "comprises . . . 0.005 to 50 mg/kg body weight" in claim 19 renders that claim and its dependents indefinite. Specifically, the quoted language recites a rate of administration of the composition, based on the body weight of the patient. However, claim 19 and its dependents are directed to compositions, not methods where a composition is administered to a patient. Thus, claim 19 does not, and cannot contain any drug administration steps which can be delimited by a limitation directed to the rate of administration of the drug. That is, a limitation directed to the rate of administration of a therapeutic agent is essentially meaningless in composition claims because composition claims, by definition, do not contain any method steps which can be limited in the manner proposed by applicant.

The recitations "high and low molecular weight ranges" and "low purity" are indefinite because they are relative terms whose metes and bounds are unclear because the relative terms "high" and "low" have an entirely subjective meaning. Because

the subject matter considered "high" or "low" by one practitioner would not necessarily be the same as the subject matter considered "high" or "low" by another practitioner, these terms fail to clearly delineate between claim-encompassed subject matter and non-claim-encompassed subject matter as required by the statute.

Similarly, the recitation "are delivered in" in claim 66 renders that claim indefinite because claim 66 is directed to a product, not a method of delivering a drug. Thus, the step of drug delivery recited in the above-quoted language of claim 66 renders that claim indefinite. Claim 66 will be construed to require the composition to be in the forms recited in the claim.

Claim 68 is indefinite because it contains a recitation excluding essential oils from the composition recited therein. The confusion lies in the fact that claim 19, from which claim 68 depends, contains the same limitation. It is therefore unclear how claim 68 is intended to depend from claim 19.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 22, 23, 36-38, 42, 47, 49, 60, 66, 68 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs (U.S. Pat. 4,303,676).

Balazs discloses a product comprising a low molecular weight hyaluronate fraction having a molecular weight of 10,000 to 200,000, a high molecular weight hyaluronate fraction having a molecular weight from 1 to 4.5 million, 50 to 400% protein (based on the weight of the hyaluronate), and water. See column 1, line 64 through column 2, line 6. In a preferred embodiment the product, designated as "HPE", is a visco-elastic liquid containing about 1% sodium hyaluronate, 0.5 to 1.5% protein and 97.5 to 98.5% water. See column 4, lines 59-68. In view of the protein present in the composition, the requirement of "low purity" is clearly met. Because the claimed ingredients are present in the claimed concentrations, a holding of anticipation is required.

It is noted that the composition is not designated as being for oral administration. However, as discussed above, the HPE composition disclosed by Balazs is in liquid form, and therefore clearly can be administered orally, and therefore can be considered a food or drink. Note that a recitation of the

intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Because Balasz's compositions can be administered orally, and because they are in the form of food and drink, as those terms are properly construed most broadly, a holding of anticipation is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP